Dustin Lance, Bar No. 8804
Jessica A. Andrew, Bar No. 12433
Cole L. Bingham, Bar No. 14131
LANCE ANDREW, P.C.
15 West South Temple, Suite 1650
Salt Lake City, Utah 84101
Office: (801) 869-6800
Facsimile: (801) 869-6801
dlance@lanceandrewlaw.com
jandrew@lanceandrewlaw.com
cbingham@lanceandrewlaw.com

Attorneys for Plaintiffs Travis and Aimee Knorr

WILLIAM D. MARLER
bmarler@marlerclark.com
MARLER CLARK. LLP, PS
1012 First Avenue, Fifth Floor
Seattle, WA 98104
Phone: (206) 346-1888
Fax: (206) 346-1898

Admitted pro hac vice

IN THE THIRD JUDICIAL DISTRICT COURT

SALT LAKE COUNTY, STATE OF UTAH

TRAVIS and AIMEE KNORR, husband and wife, Plaintiffs, v. DWIGHT & LINFORD ENTERPRISES LLC, d/b/a JIMMY JOHN'S, a Utah corporation, Defendant.	**PLAINTIFFS' MOTION FOR LEAVE TO FILE SECOND AMENDED COMPLAINT TO ADD PUNITIVE DAMAGES CLAIM** **(Tier 3)** Case No. 200902468 Judge: L. Douglas Hogan

NOW COME Plaintiffs TRAVIS and AIMEE KNORR by and through their attorneys, Dustin Lance of LANCE ANDREW, P.C., and William D. Marler of MARLER CLARK, LLP, PS, and respectfully move to amend their complaint against Defendant DWIGHT & LINFORD ENTERPRISES LLC, d/b/a JIMMY JOHN's, (hereinafter "Defendant") to add a claim for punitive damages, and in support of this request, state as follows:

I. INTRODUCTION

This matter arises out of an outbreak of Shiga toxin-producing *E. coli* (STEC) O103 that occurred in the early months of 2020. After thorough investigation and laboratory testing, the Utah Department of Health and Centers for Disease Control and Prevention (CDC) linked this outbreak to clover sprouts used by Defendant to manufacture its sandwiches.

After purchasing and consuming a Billy Club Sandwich from Defendant's restaurant on February 21, 2020, Plaintiff Travis Knorr began to develop symptoms consistent with a STEC O103 infection and within the typical STEC incubation period on February 26, 2020. He was later diagnosed with STEC O103:H2 via stool sample testing, and the Utah Department of Health further conclusively determined, using whole genome sequencing (WGS), that he was a confirmed case in the 2020 STEC O103 outbreak linked to clover sprouts from Jimmy John's (CDC cluster code 2002IAEXW-1).

Plaintiffs filed this lawsuit on March 31, 2020, alleging that the sandwich Travis Knorr consumed from Defendant's restaurant was the source of bacteria that caused his illness. The discovery process, as well as plaintiff's investigation of Defendant Jimmy John's history of foodborne illness outbreaks, has revealed that Defendant has been linked to numerous other sprouts-related outbreaks.[1] Jimmy John's Franchise, LLC was linked to three outbreaks between 2008 and late 2010, the last of which led to 140 Illnesses.[2] Following the November 2010 outbreak, then owner John Liautaud stated in January of

[1] *See* Attachment A - Plaintiffs' Proposed Second Amended Complaint Paragraphs 13 – 20.
[2] Attachment B – Expert report of Benjamin Chapman, PhD, at 5.

2011 that the chain would replace would replace alfalfa sprouts with clover sprouts as they were allegedly easier to clean.[3]

Less than one year later, Jimmy John's was again implicated in a sprouts-related outbreak prompting a February 2012 announcement that Jimmy John's Franchise, LLC would be removing all raw clover sprouts from their menus.[4] However, three months later, at a meeting with the FDA, Defendant changed its position and stated that it would serve only clover sprouts sourced from specific suppliers.[5]

Since that meeting, the FDA has documented three additional sprouts-related outbreaks implicating Jimmy John's establishments where traceback investigations show Defendant has used suppliers that were not on its approved supplier list in 2012.[6] In his report, Ben Chapman, PhD notes that in over 20 years as a food safety professional, he has never encountered a situation "where a firm said they would do something in an official meeting with FDA, and then eventually decided to do something else."[7]

Following a November 2019 outbreak of *E. coli* 0103 (STEC) linked to sprouts served at 15 Jimmy John's locations in Iowa, the FDA sent Jimmy John's Franchise, LLC a warning letter on February 21, 2020, five days before Travis Knorr began exhibiting symptoms as part of the Jimmy John's linked 2020 *E. coli* 0103 outbreak.[8] In that letter, the FDA detailed evidence from five outbreaks that, the FDA said, demonstrated that Jimmy John's, LLC, through its franchised restaurants, "engaged in a pattern of receiving and offering for sale

[3] *Id.*
[4] *Id.*
[5] *Id.*, at 6.
[6] Attachment C, Warning Letter to Jimmy John's Franchise, LLC, at 3.
[7] Attachment B, at 6.
[8] *See* Attachment C.

adulterated fresh produce, specifically clover sprouts and cucumbers."[9] The letter went on to state that "[t]aken together, these outbreaks, which spanned over the past seven years and impacted no fewer than seventeen states demonstrate the corporate-wide supplier control mechanisms you have in place for receiving fresh produce are inadequate."[10]

Similarly, in his expert report, Benjamin Chapman, PhD, noted that, in his opinion, Jimmy John's Franchise, LLC's decision to ignore evidence of the dangers of selling sprouts; failure to provide adequate resources to food handlers, specifically to control cross-contamination from sprouts; and failure to practice good risk communication towards customers "demonstrates a poor food safety culture."[11] He also noted in his report that cross-contamination from adulterated sprouts "more likely than not led to illnesses with Plaintiffs Knorr and McDonald as they did not report eating sprouts directly but have whole genome matches with the outbreak strain."[12]

In spite of significant available data on the dangers posed by sprout sales for consumption,[13] Defendant's experience with several sprouts–related outbreaks, and Defendant's acknowledgement of the dangers of serving sprouts during the 2012 meeting with the FDA,[14] Defendant continued to offer and sell raw sprouts leading to several outbreaks of life-threatening foodborne illness, including the 2020 outbreak that injured Plaintiff Travis Knorr. Given Defendant's blatant and at times sarcastic disregard of the dangers associated with serving sprouts,[15] Plaintiffs move to add to their complaint a claim

[9] Attachment C, at 1.
[10] *Id.*, at 3.
[11] Attachment B, at 1.
[12] *Id.* at 4.
[13] *See* Sprout-associated--outbreaks-4-5-21.xls attached to Attachment B.
[14] *See* Attachment C.
[15] *See* Attachment B, at 6, 7.

for punitive damages. Plaintiffs' counsel represents two other Plaintiffs who were also sickened in this outbreak and will move to add a claim for punitive damages, as described below, in all three cases, all of which are filed in this Court.

II. AUTHORITY

a) Plaintiffs' Motion to Amend Should be Granted

Utah Rules of Civil Procedure, Rule 15(a)(2) states that after a responsive pleading has been served, "a party may amend its pleading only with the court's permission or the opposing party's written consent." The rule also states that "[t]he court should freely give permission when justice requires." Utah R. Civ. P. 15(a)(2). In considering a motion to amend a complaint, however, a court must also consider whether the opposing party would be put to unavoidable prejudice by having an issue adjudicated for which he had not had time to prepare. *Bekins Bar V Ranch v. Huth*, 664 P.2d 455, 464 (Utah 1983).

On February 3, 2021, this Court ordered that fact discovery would be extended until July 15, 2021, based on a stipulated motion by the parties. Further, the claim for relief which the Plaintiffs wish to add is based on the same cause of action pled in the Plaintiffs' original complaint; and the basis for adding punitive damages to the Plaintiffs' complaint is information known entirely by Defendant. Given that Defendant has ample time to prepare a defense to punitive damages considering the significant fact discovery period still remaining, and given that the factual basis of Plaintiffs' proposed amendment is entirely known to Defendant, Defendant will not be prejudiced by Plaintiffs' addition of punitive damages to their original complaint.

Further, Utah Rules of Civil Procedure, Rule 54(c) states that, excluding default judgments, all other judgments "should grant the relief to which each party is entitled,

even if the party has not demanded that relief in its pleadings." In reviewing a trial court's denial of a plaintiff's motion to add punitive damages, the Supreme Court of Utah stated that such a case "must be viewed against the backdrop of [Utah R.Civ.P. 54(c)]." *Behrens v. Raleigh Hills Hosp., Inc.*, 675 P.2d 1179, 1182 (Utah 1983). The Court in *Behrens* reasoned that, under Utah R.Civ.P. 54(c), if the plaintiff was able to present sufficient foundational evidence at trial, she could then claim punitive damages without a formal amendment to the pleadings. *Id.* As such, amending a complaint to add a claim for punitive damages cannot prejudice the defendant, as the Court determined in *Behrens*.

For these reasons, this Court should grant the Plaintiffs' motion to amend their complaint and add a claim for punitive damages.

b) Punitive Damages are Appropriate in This Case

Utah Code §78B-8-201(1)(a) states the basis for an award of punitive damages as follows:

> Except as otherwise provided by statute, punitive damages may be awarded only if compensatory or general damages are awarded and it is established by clear and convincing evidence that the acts or omissions of the tortfeasor are the result of willful and malicious or intentionally fraudulent conduct, or conduct that manifests a knowing and reckless indifference toward, and a disregard of, the rights of others.

Utah courts have also long permitted recovery of punitive damages in personal injury cases. *See Behrens v. Raleigh Hills Hosp., Inc.,* 675 P.2d at 1185, *Johnson v. Rogers,* 763 P.2d 771 (Utah 1988).

Similarly, while the Utah Product Liability Act does not address the issue of punitive damages, but rather states that a "complaint shall merely pray for such damages as are reasonable in the premises." Utah Code Ann. §78B–6–704 (2010), Utah courts have allowed plaintiffs to make claims for punitive damages under the Act. *See Simantob*

v. Mullican Flooring, L.P., 2010 WL 2486549 (Utah 2010). Given that Plaintiffs have pled with specificity a claim of strict liability based on an adulterated food product, this Court should find the addition of punitive damages permissible and grant Plaintiffs' motion to amend their complaint.

III. CONCLUSION

WHEREFORE, Plaintiffs respectfully pray that this Court grant their Motion to add a Claim for Punitive Damages against Defendant.

DATED this 19th day of April, 2021.

/s/ *Dustin Lance*
Dustin Lance
LANCE ANDREW, P.C.

/s/ *William D. Marler*
William D. Marler
MARLER CLARK, LLP, PS

Attorneys for Plaintiffs Travis and Aimee Knorr

CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of April, 2021, I caused the foregoing to be served by the manner indicated below:

Matthew D. Church Brody L. Hyer Plant, Christensen & Kanell 136 East South Temple, Suite 1700 Salt Lake City, UT 84111 mchurch@pckutah.com bhyer@pckutah.com *Attorneys for Defendant Dwight & Linford Enterprises, LLC*	(X) ( ) ( ) ( ) ( ) ( )	E-file U.S. Mail, Postage Prepaid Hand Delivered Overnight Mail Facsimile E-mail
Anna Nelson Morgan Minnock Rice & Miner, LC 136 South Main Street Salt Lake City, UT 84101 anelson@mmrm.com *Attorney for Third-Party Defendant Reynolds Industries, Inc.*	(X) ( ) ( ) ( ) ( ) ( )	E-file U.S. Mail, Postage Prepaid Hand Delivered Overnight Mail Facsimile E-mail
Kevin J. Simon Strachan Strachan & Simon 401 Main Street Park City, UT 84060 kevin@strachanlaw.com *Attorney for Third-Party Defendant A&Z, LLC*	(X) ( ) ( ) ( ) ( ) ( )	E-file U.S. Mail, Postage Prepaid Hand Delivered Overnight Mail Facsimile E-mail
Bentley J. Tolk Rodger M. Burge Kevin G. Heiner Parr Brown Gee & Loveless 101 South 200 East, Suite 700 Salt Lake City, UT 84111 btolk@parrbrown.com rburge@parrbrown.com kheiner@parrbrown.com *Attorneys for International Specialty Supply*	(X) ( ) ( ) ( ) ( ) ( )	E-file U.S. Mail, Postage Prepaid Hand Delivered Overnight Mail Facsimile E-mail

Christopher R. Hogle Chris D. Mack Holland & Hart 222 South Main Street, Suite 2200 Salt Lake City, UT 84101 crhogle@hollandhart.com cdmack@hollandhart.com *Attorney for Third-Party Defendant Sysco*	(X) E-file ( ) U.S. Mail, Postage Prepaid ( ) Hand Delivered ( ) Overnight Mail ( ) Facsimile ( ) E-mail

/s/ Tiffini Moss

Exhibit A

DUSTIN LANCE, Bar No. 8804
dlance@lanceandrewlaw.com
LANCE ANDREW, P.C.
15 West South Temple, Suite 1650
Salt Lake City, Utah 84101
Telephone: (801) 869-6800
Facsimile: (801) 869-6801

Attorneys for Plaintiffs Travis and Aimee Knorr

WILLIAM D. MARLER
bmarler@marlerclark.com
MARLER CLARK, LLP, PS
1012 First Avenue, Fifth Floor
Seattle, WA 98104
Phone: (206) 346-1888
Fax: (206) 346-1898

Admitted pro hac vice

IN THE THIRD JUDICIAL DISTRICT COURT

SALT LAKE COUNTY, STATE OF UTAH

TRAVIS and AIMEE KNORR, husband and wife, Plaintiffs, v. DWIGHT & LINFORD ENTERPRISES, LLC, d/b/a JIMMY JOHN's, a Utah corporation, Defendant.	**SECOND AMENDED COMPLAINT** **(JURY TRIAL DEMANDED)** **(Tier 3)** Case No. 200902468 Judge L. Douglas Hogan

Plaintiffs TRAVIS and AIMEE KNORR (hereinafter "Plaintiffs") complain against Defendant DWIGHT & LINFORD ENTERPRISES, LLC, d/b/a JIMMY JOHN'S (hereinafter "Jimmy John's") as follows:

PARTIES

1. Travis and Aimee Knorr are residents of the State of Utah.

2. Dwight & Linford Enterprises, LLC, d/b/a, Jimmy John's (hereinafter "Defendant" or "Jimmy John's") is a limited liability company, organized and existing

under the laws of the State of Utah, with its corporate headquarters and principal place of business located 81 West 3300 South, Suite B, Salt Lake City, Utah 84115. At all times relevant to this complaint, Jimmy John's owned and operated the Jimmy John's restaurant located at 13893 Bangerter Parkway, Draper, Utah 84020.

JURISDICTION AND VENUE

3. The Third Judicial District Court in and for Salt Lake County, State of Utah, has jurisdiction of the claims asserted below pursuant to the provision of §78A-5-102, Utah Code Ann. (1953 as amended).

4. Venue is properly laid before the Third Judicial District Court in and for Salt Lake County, State of Utah, pursuant to the provisions of §78B-3-307, Utah Code Ann. (1953 as amended), in that the causes of action alleged below arose within Salt Lake County, State of Utah.

5. Pursuant to Rule 26(c)(3), of the New Utah Rules of Civil Procedure, the amount in controversy exceeds $300,000.00, qualifying this claim for a Tier 3 standard discovery.

GENERAL ALLEGATIONS

THE JIMMY JOHN'S E. COLI OUTBREAK

6. The Centers for Disease Control and Prevention (CDC), public health and regulatory officials in several states, and the U.S. Food and Drug Administration (FDA) are investigating a multi-state outbreak of *E. coli* O103 infections linked to clover sprouts.

7. As of April 22, 2020, 51 people infected with the outbreak strain of *E. coli* O103 have been reported from ten states: Florida (1); Idaho (1); Illinois (7); Iowa (3); Missouri (1); New York (1); Texas (1); Utah (34); Virginia (1); and Wyoming (1).

8. Illnesses started on dates ranging from January 6, 2020 to March 15, 2020. Ill people range in age from 1 to 79 years, with a median age of 29. Fifty-five percent of ill people were female. Three people were hospitalized. No deaths were reported.

9. Epidemiologic, traceback, and laboratory evidence indicate that clover sprouts are the source of this outbreak. State and local public health officials are continuing to interview ill people to determine what they ate and other exposures they had in the week before their illness started. Eighteen (56%) of 32 people interviewed reported eating sprouts. Seventeen (63%) of 27 people interviewed reported eating sprouts at a Jimmy John's restaurant.

10. Jimmy John's LLC reported that all of their restaurants stopped serving clover sprouts on February 24, 2020.

11. The FDA identified the outbreak strain of *E. coli* O103 in samples of Chicago Indoor Garden products that contain sprouts. On March 16, 2020, Chicago Indoor Garden recalled all products containing red clover sprouts.

12. FDA's traceback investigation has shown that a common seed lot was used to grow the sprouts recalled by Chicago Indoor Garden and the sprouts that were served at Jimmy John's locations where people sickened in the current outbreak reported eating. The same seed lot was also used to grow sprouts linked to an outbreak of the same strain of *E. coli* O103 infections in 2019. As of April 22, 2020, this outbreak appears to be over.

A HISTORY OF JIMMY JOHN'S SPROUTS-RELATED OUTBREAKS

13. **Iowa 2019 Jimmy John's Restaurant Sprouts *E. coli* O103 Outbreak**. 22 Sickened – The Iowa Department of Public Health reported that, as of January 7, 2020, 100 percent of the individuals interviewed had reported eating at one or more of 15 Jimmy John's restaurants. The Iowa Department of Inspections and Appeals determined that several of those restaurants had received clover sprouts during the period of interest. Samples of sprouts and sprout irrigation water collected from the firm that supplied those sprouts yielded a strain of *E. coli* O103 that was highly related to the outbreak strain by whole genome sequencing and genetic subtyping.

14. **Multi-state *Salmonella* Montevideo Outbreak Jimmy John's Restaurant Sprouts 2018.** 10 Sickened – The CDC reported that, as of February 28, 2018, eight of the ten people confirmed as part of this outbreak reported eating meals at Jimmy John's restaurants in Illinois and Wisconsin, and all eight reported eating raw sprouts as part of their meals. One of the other individuals reported purchasing sprouts from a grocery store in Minnesota. All of the *Salmonella* Montevideo infections were found to be closely related by whole genome sequencing. According to the FDA, evidence, including invoices collected by local and state agencies, supported a finding that sprouts were the vehicle for this outbreak.

15. **Multistate *E. coli* O121 Outbreak Jimmy John's Restaurants Sprouts 2014.** 19 Sickened – A CDC report from August of 2014 stated that 19 people in Idaho, Montana, Michigan, Utah, California, and Washington were infected with *E. coli* O121. 13 of 16 people interviewed reported having eaten raw clover sprouts prior to falling

ill. The FDA's traceback investigation revealed seven points of service as the locations of these sprout exposures, five of which were identified as Jimmy John's restaurants. All of the sprouts served at those seven locations were sourced from the same grower.

16. **Multistate *E. coli* O26 Outbreak Jimmy John's Restaurants Sprouts 2012.** 29 Sickened – As of April 5, 2012, the CDC reported that 23 of 27 people interviewed reported eating sprouts at one of six Jimmy John's restaurants in the seven days preceding their illness. Through a traceback investigation, the FDA identified a single lot of seed grown and distributed through multiple sprouting firms that supplied the six Jimmy John's restaurants that were implicated in the outbreak.

17. **Sprouters Northwest, Jimmy John's Restaurants Clover *Salmonella* Sprouts Outbreak 2010.** 7 Sickened – Sprouters Northwest of Kent, WA, issued a product recall after the company's clover sprouts had been implicated in an outbreak of *Salmonella* Newport in Oregon and Washington. At least some of the cases had consumed clover sprouts while at a Jimmy John's restaurant. Concurrent with this outbreak, a separate outbreak of *Salmonella,* serotype I4,[5],12:i:- involving alfalfa sprouts served at Jimmy John's restaurants was under investigation. The recall of Sprouters Northwest products included: clover, clover and onion, spicy sprouts, and deli sprouts. The Sprouters Northwest products had been sold to grocery stores and wholesale operations in Washington, Oregon, Idaho, Alaska, British Columbia, Saskatchewan, and Alberta. The FDA inspection found serious sanitary violations.

18. **Multistate *Salmonella* Outbreak, Tiny Greens Organic Farm, Jimmy John's Restaurants Alfalfa Sprouts 2010.** 140 Sickened – On December 17,

the Illinois Department of Health announced that an investigation was underway into an outbreak of *Salmonella*, serotype I4,[5],12:i:-. Many of the Illinois patients had eaten alfalfa sprouts at various Jimmy John's restaurants in the Illinois counties of Adams, Champaign, Cook, DuPage, Kankakee, Macon, McHenry, McLean, Peoria, and Will. The sprouts were suspected to be the cause of the illnesses. On December 21 of that year, Jimmy John Liautaud, the owner of the franchised restaurant chain, requested that all franchisees remove all sprouts from the menu as a "precautionary" measure. On December 23, 2010, the Centers for Disease Control revealed that outbreak cases had been detected in other states, and that the outbreak was linked with eating alfalfa sprouts from a nationwide sandwich chain. On December 26, preliminary results of the investigation indicated a link to eating Tiny Greens' Alfalfa Sprouts at Jimmy John's restaurants. The FDA subsequently advised consumers and restaurants to avoid Tiny Greens Brand Alfalfa Sprouts and Spicy Sprouts produced by Tiny Greens Organic Farm of Urbana, Illinois. The Spicy Sprouts contained alfalfa, radish, and clover sprouts. On January 14, 2011, it was revealed that the FDA had isolated *Salmonella* serotype I4,[5],12:i:- from a water runoff sample collected from Tiny Greens Organic Farm; the *Salmonella* isolated was indistinguishable from the outbreak strain. The several FDA inspections of the sprout growing facility revealed factors that likely led to contamination of the sprouts.

19. **CW Sprouts, Inc., SunSprout Sprouts, "restaurant chain (Chain A)," a.k.a. Jimmy John's *Salmonella* Outbreak 2009.** 256 Sickened – In February 2009, Nebraska Department of Health and Human Services officials identified six isolates

of *Salmonella* Saintpaul. Although this is a common strain of *Salmonella*, during 2008, only three cases had been detected in Nebraska, and only four subtypes of this outbreak strain had been identified in 2008 in the entire USA. As additional reports were made, a case control study was conducted; alfalfa sprout consumption was found to be significantly related to illness. The initial tracebacks of the sprouts indicated that, although the sprouts had been distributed by various companies, the sprouts from the first cases originated from the same sprouting facility in Omaha, NE. Forty-two of the illnesses beginning on March 15 were attributed to sprout growing facilities in other states; these facilities had obtained seed from the same seed producer, Caudill Seed Company of Kentucky. The implicated seeds had been sold in many states. On April 26, the FDA and CDC recommended that consumers not eat raw alfalfa sprouts, including sprout blends containing alfalfa sprouts. In May, the FDA alerted sprout growers and retailers that a seed supplier, Caudill Seed Company of Kentucky, was withdrawing all alfalfa seeds with a specific three-digit prefix. Many of the illnesses occurred at "restaurant chain (Chain A)," according to the CDC, which generally does not identify specific business.

20. **Jimmy John's Restaurant Alfalfa Sprouts and Iceberg Lettuce *E. coli* Outbreak 2008.** 28 Sickened – Several University of Colorado students from one sorority became ill with symptoms of bloody diarrhea and cramping. Additional illnesses were reported. *E. coli* O157:NM(H-) was determined to be the cause. Consumption of alfalfa sprouts at the Jimmy John's Restaurants in Boulder County and Adams County were risk factors for illness. In addition, the environmental investigation identified

Boulder Jimmy John's food handlers who were infected with *E. coli* and who had worked while ill. The health department investigation found a number of critical food-handling violations, including inadequate handwashing. The fourteen isolates from confirmed cases were a genetic match to one another.

TRAVIS KNORR'S E. COLI ILLNESS

21. The plaintiffs, by and through this reference, hereby incorporate paragraphs nos. 1 through 20, above, as if fully set forth herein.

22. Travis and Aimee Knorr reside in Saratoga Springs, Utah.

23. On February 21, 2020, Travis ordered a Billy Club sandwich ("the Sandwich") from the Jimmy John's located at 13893 Bangerter Parkway in Draper, Utah. The Sandwich was delivered to his workplace, where he subsequently consumed the Sandwich upon its arrival.

24. On February 26, 2020, Travis began experiencing the onset of *E. coli* symptoms, including abdominal cramping and diarrhea. His symptoms eventually grew in severity to the point that he had to leave work early on February 27.

25. Travis visited his family physician on March 2, 2020 because his symptoms continued unabated. His doctor started him on an antibiotic for a possible *C. difficile* infection and also sent him home with a stool kit to be returned for further analysis. Travis returned the stool sample to his physician the next day.

26. On March 6, 2020, Travis's physician notified him that his stool sample tested positive for *E. coli*.

27. After learning of his diagnosis, Travis went to Mountain Point Medical Center emergency room. Scans and bloodwork revealed he was suffering from acute kidney failure, and he was admitted on March 8, 2020 for treatment and additional testing and observation.

28. Travis's kidney function steadily improved into March 10, when he was finally discharged from the hospital. That same day, the Utah County Health department contacted Travis about his *E. coli* exposure and illness.

29. Unfortunately, Travis began experiencing a relapse of diarrhea and abdominal cramping on March 14, 2020, prompting him to eventually return to his family physician on March 17, 2020. His doctor performed additional kidney function blood tests and collected another stool sample.

30. Travis also attended an appointment with his gastroenterologist on March 20, who proscribed medication for his stomach cramping.

31. On March 21, Travis learned that he now suffered from a *C. diff* infection. He was prescribed antibiotics, and his doctor also informed him that his *E. coli* infection had subsided.

32. Travis continued to recover through the end of March, and, on March 24, 2020, he was again contacted by the Utah County Health Department who informed him that the *E. coli* strain that had sickened him was identified as *E. coli* O103:H2 and given the cluster codes 202002STEC002 by the Utah County Health Department and 2002IAEXW-1 by CDC.

FIRST CLAIM FOR RELIEF
(Strict Liability)

33. The plaintiffs, by and through this reference, hereby incorporate paragraphs nos. 1 through 32, above, as if fully set forth herein.

34. Jimmy John's manufactured and sold the adulterated food product, i.e. the Sandwich, that is the subject of the action.

35. Jimmy John's knew or should have known that the use of sprouts in their restaurants would, with a high degree of probably, result in the adulteration of food products sold to their customers.

36. The adulterated food product that Jimmy John's manufactured, distributed, or sold was, at the time it left Jimmy John's control, defective and unreasonably dangerous for its ordinary and expected use because it contained *E. coli* O103, a harmful pathogen.

37. The adulterated food product that Jimmy John's manufactured, distributed, or sold reached Travis without any change in its defective condition.

38. The adulterated food product that Jimmy John's manufactured, distributed, or sold was used in the manner expected and intended, and was consumed by Travis.

39. Travis suffered injury and damages as a direct and proximate result of the defective and unreasonably dangerous condition of the adulterated food product that Jimmy John's manufactured, distributed, or sold.

40. The plaintiffs have further suffered a loss of consortium as a direct and proximate result of the defective and unreasonably dangerous condition of the adulterated food product that Jimmy John's manufactured, distributed, or sold.

SECOND CLAIM FOR RELIEF
(Negligence)

41. The plaintiffs, by and through this reference, hereby incorporate paragraphs nos. 1 through 40, above, as if fully set forth herein.

42. Jimmy John's owed Travis a duty to use reasonable care in the manufacture, distribution, and sale of its food product, the observance of which duty would have prevented or eliminated the risk that Jimmy John's food products would become contaminated by *E. coli* O103 or any other dangerous pathogen.

43. Jimmy John's breached this duty.

44. Jimmy John's had a duty to comply with all statutes, laws, regulations, or safety codes pertaining to the manufacture, distribution, storage, and sale of its food products.

45. Jimmy John's failed to comply with its duty and was therefore negligent.

46. Travis is among the class of persons designed to be protected by these statutes, laws, regulations, safety codes or provision pertaining to the manufacture, distribution, storage, and sale of similar food products.

47. Jimmy John's had a duty to properly supervise, train, and monitor its employees, and to ensure its employees' compliance with all applicable statutes, laws,

regulations, or safety codes pertaining to the manufacture, distribution, storage, and sale of similar food products.

48. Jimmy John's failed to do so and was therefore negligent.

49. Jimmy John's further had a duty to use ingredients, supplies, and other constituent materials that were reasonably safe, wholesome, free of defects, and that otherwise complied with applicable federal, state, and local laws, ordinances, and regulations, and that were clean, free from adulteration, and safe for human consumption.

50. Jimmy John's failed to do so and was therefore negligent.

51. As a direct and proximate result of Jimmy John's acts and omissions of negligence, Travis sustained injuries and damages in an amount to be proven at trial.

52. As a further direct and proximate result of Jimmy John's negligence, the plaintiffs have suffered a loss of consortium.

THIRD CLAIM FOR RELIEF
(Negligence *Per Se*)

53. The plaintiffs, by and through this reference, hereby incorporate paragraphs nos. 1 through 52, above, as if fully set forth herein.

54. Jimmy John's had a duty to comply with all applicable state and federal regulations intended to ensure the purity and safety of its food product, including the requirements of the Federal Food, Drug and Cosmetics Act (21 U.S.C. § 301 *et seq*.).

55. Jimmy John's failed to comply with the provisions of the health and safety acts identified above, and, as a result, was negligent *per se* in its manufacture, distribution, and sale of food adulterated with *E. coli* O103, a harmful pathogen.

56. As a direct and proximate result of conduct by Jimmy John's that was negligent per se, Travis sustained damages in an amount to be proven at trial.

57. As a further direct and proximate result of Jimmy John's negligence per se, the plaintiffs have suffered a loss of consortium.

DAMAGES

58. Plaintiffs have suffered general, special, incidental, and consequential damages as the direct and proximate result of the acts and omissions of Jimmy John's, in an amount that shall be fully proven at the time of trial. These damages include, but are not limited to: damages for general pain and suffering; damages for loss of enjoyment of life, both past and future; medical and medical related expenses, both past and future; travel and travel-related expenses, past and future; emotional distress, past and future; pharmaceutical expenses, past and future; loss of consortium, past and future; and all other ordinary, incidental, or consequential damages that would or could be reasonably anticipated to arise under the circumstances.

59. Plaintiffs request punitive damages in this matter based on the conduct of Jimmy John's, given Jimmy John's knowledge that serving and using sprouts in their restaurant would, to a high degree of probability, result in substantial harm to a customer, and Defendant's reckless and blatant disregard of this danger.

JURY DEMAND

Plaintiffs hereby demand a jury trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Jimmy John's as follows:

A. Ordering compensation for all general, special, incidental, and consequential damages suffered by the plaintiffs as a result of Jimmy John's conduct;

B. Ordering compensation in the form of punitive damages as a result of Jimmy John's conduct;

C. Awarding plaintiffs their reasonable attorneys' fees and costs, to the fullest extent allowed by law; and

D. Granting all such additional and/or further relief as this Court deems just and equitable.

DATED this ____ day of April 2021.

Dustin Lance
LANCE ANDREW, P.C.

William D. Marler
MARLER CLARK, LLP, PS

Attorneys for Plaintiffs Travis and Aimee Knorr

Exhibit B

April 5, 2021

Mr. William Marler, Esq.
Marler Clark, LLP, PS
1012 First Avenue, Fifth Floor
Seattle, Washington 98104-1008

RE: Case Reviews, *E. coli* O103 Outbreak

Dear Mr. Marler:

I have reviewed documents related to the 2020 Jimmy John's Franchise, LLC linked outbreak including depositions, illness questionnaires, medical records and publicly available records. My assessment, and expert opinion, is based on my review of these documents, the history of sprouted seed related outbreaks, food safety research literature, popular press related to previous Jimmy John's Franchise, LLC outbreaks, and regulatory documents from the U.S. Food and Drug Administration (FDA).

In my professional opinion, Jimmy John's Franchise, LLC's decision to repeatedly ignore the ever-growing mountain of evidence related to the risks associated with selling raw sprouted seeds, and to not provide the resources necessary to food handlers to control cross-contamination when preparing foods in the same restaurant as where sprouts are handled, coupled with its failure to practice good risk communication towards customers about the hazards associated with consuming raw sprouted seeds, demonstrates a poor food safety culture.

The concept of food safety culture has been pointed to as the root of what keeps the global food supply safe from contamination and has been embraced by the FDA as part of their modernization of food regulation and the Global Food Safety Initiative.

A culture of food safety is built on a set of shared values that operators and their staff follow to produce and provide food in the safest manner. Maintaining a good food safety culture means that operators and staff know the risks associated with the products or meals they produce, know why managing the risks is important, and effectively manage those risks in a demonstrable way. In an organization with a good food safety culture, individuals are expected to enact practices that represent the shared value system, point out where others may fail, and learn from others' mistakes. In short, a positive food safety culture means food safety is important within the organization and is supported from the top down, empowering employees to protect customers above all else.

In my professional opinion, the best food producers, processors, retailers and restaurants, many of whom participate in the Global Food Safety Initiative, go above and beyond minimal government and auditor standards and implement strong food safety programs. There are several examples of businesses that do this, many of whom have been awarded the International Association of Food Protection's Black Pearl award

(IAFP, 2020), which is presented in recognition of a company's outstanding achievement in corporate excellence in food safety and quality. The best organizations use their own staff to demand ingredients from the best suppliers; use a mixture of encouragement and enforcement to foster safe practices in food purchasing, distribution and training; and communicate how risks are being reduced directly to consumers.

Frequent information sharing and regular communication about foodborne risks amongst executives, middle management, and frontline food handlers is also important to support a culture of food safety (Yiannas, 2009). Many food safety experts have advocated for an executive level position to access food safety risks, compose and communicate a food safety mission statement, establish a food safety budget, and manage the food safety responsibilities of employees.

Sprouts present a unique food safety challenge compared to other fresh produce. The sprouting process of high humidity and high temperatures provides optimal conditions for the growth and proliferation of pathogenic bacteria if introduced on the seed or at any other time in the sprouting process.

The food safety community has been aware of the risks associated with sprouted seeds for at least three decades.

Sprouted seeds have been known to be heavily colonized by bacterial biofilms during the sprouting process and are well recognized for their ability to support microbiological loads (Fett, 2000). Despite this bacterial community, sprouts retain acceptable sensory characteristics that appeal to consumers and, as such, cannot be effectively evaluated using spoilage sensory tests (odor, physical appearance, taste).

Sprout risk reduction during sprout production began appearing in scientific journals in 1995 (Ponka et al, 1995; Health Canada, 1996; Jaquette et al, 1996; Puohiniemi et al, 1997). Research published in a prominent food safety journal in 1996 stated that the sprouting environment, which facilitated the growth of Salmonella, was a serious public health concern requiring urgent attention based on the recent association of sprouts with foodborne illness. The researchers stressed that the results were not a recommendation for people to avoid sprouts at salad bars, but rather should serve as a wake-up call for those who produced and prepared the product.

Over twenty years ago, in 1999, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) produced a report on microbiological safety evaluations and recommendations for sprouted seeds in which the authors concluded that contaminated seed, and thus sprouters, was the likely source for most reported sprout-associated outbreaks (NACMCF, 1999).

The first consumer warning about sprouts was issued by the U.S. Centers for Disease Control (CDC) in 1997. By July 9, 1999, FDA had advised all Americans to be aware of the risks associated with eating raw sprouts and that the best way to control the risk was to simply not eat raw sprouts.

In response to NACMCF recommendations, the FDA developed guidelines for the sprout industry in October 1999. This guidance identified a number of areas, from the farm to the sprouting facility, where the FDA believed immediate steps should be taken to reduce the risk of sprout-associated foodborne illness (FDA, 1999). These included recommendations that seeds should be subjected to one or more approved treatments for reducing pathogens on seeds and sprouts; and that treatment should be supplemented with microbiological testing of the spent irrigation water from each production lot to minimize the potential for distribution of a contaminated batch.

Since the late 1990s, the sprout production industry, regulatory agencies, and the academic community have been collaborating to improve the microbiological safety of raw sprouts, including the implementation of Good Manufacturing Practices (GMP), by establishing guidelines for safe sprout production and chemical disinfection of seed prior to sprouting. However, guidelines and best practices are only as good as their implementation. The consumption of raw sprouts is considered high-risk. As a result, sprouted seeds have been called out by the U.S. Centers for Disease Control and Prevention (CDC) as a food to avoid especially for young, elderly and immuno-compromised persons, and are treated differently from other regulated fresh produce items by FDA. This can be seen in both the Food Safety Modernization Act (FSMA) in 2011, as well as in the U.S. Model Food Code going back prior to 2001, in which sprouted seeds were considered to be potentially hazardous foods and were not permitted to be served to highly susceptible populations.

More recently, there has been numerous presentations, scientific posters, and symposia at the International Association for Food Protection's annual meetings, the preeminent gathering of the food safety community. These include the 2012 symposium entitled, "Sprout Safety: What We've Done, What We've Learned and How We Can Continue to Move Forward," and 2014's "Microgreens and Sprouts under Microscope: Similarities and Differences in Botanic Structure, Agricultural Practices, and Food Safety Risks." In addition, a review of the past 10 years of meeting abstracts reveals that there have been over 50 posters and 80 presentations on sprout safety. Sprouted seeds food safety is amongst the most important and long-standing topics in the food safety world.

In 2012 FDA and the Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH) formed the Sprouts Safety Alliance (SSA) in an attempt to address some of these issues. The mission of this public-private alliance is to develop a core curriculum with training and outreach programs for stakeholders in the sprout production community in order to enhance the industry's understanding and implementation of best practices for promoting sprout safety, and of pending sprout safety regulatory requirements. The SSA has also provided guidance and inspection/audit checklists for buyers of sprouted seeds (SSA, 2011). In my professional opinion, anyone who is purchasing sprouts with a positive food safety culture should not only be aware of these resources, but should further be employing the SSA approach to supply chain verification.

Handling sprouted seeds in a restaurant setting can provide challenges, whether contaminated or not. This is evidenced by the FDA Model Food Code requirements to hold sprouted seeds under temperature control (designating them a Time/Temperature Control for Safety Food) and for restaurants who sprout their own seeds to apply for a variance to the code and implement a HACCP plan. This is not only because the sprouted seeds themselves provide a risk when consumed, but also because handling them leads to increased risks of cross-contamination that need to be controlled through the reduction measures. Essentially, having the increased likelihood that a pathogen enters on the sprouts, food employees/handlers need to be aware that there is a potential to move contamination from the sprouts to other foods, resulting in patrons who did not even consume the sprouts to become ill. This is not just a theoretical risk; it has been highlighted in multiple previous outbreak investigations. As an example, a historic case study in sprouted seed food safety demonstrates that cross-contamination happens. In a 1995 multinational outbreak of *Salmonella* enterica Serotype Newport infections due to contaminated alfalfa sprouts, public health experts wrote that they identified 133 cases in Oregon and British Columbia; 124 (93%) occurred in patients older than 18 years; 87 (65%) were female. Case patients were more likely than community control subjects to report having eaten alfalfa sprouts in the 5 days preceding illness (41% [17/41] vs 4% [3/75]; OR, 17.0; 95% confidence interval, 4.3-96.0). But in contrast to most foodborne outbreaks, only a minority of cases (in this outbreak, 41%) recalled eating the implicated food. This is likely because of cross-contamination of salad and sandwich bars or sprouts' concealed presence in other foods (Van Beneden et al, 1999).

Retailers, restaurants, and other food service operators who have served any potentially contaminated products need to be concerned about cross-contamination through hands (gloved or bare), food contact surfaces, and utensils through contact with the potentially contaminated products. Cross-contamination and handwashing have been identified through multiple independent studies, as well as the FDA's risk factor studies, as amongst the most problematic of food handlers' practices within a foodservice setting (FDA, 2018). In my professional opinion, cross-contamination within the restaurant also more likely than not led to illnesses with Plaintiffs Knoor and McDonald as they did not report eating sprouts directly but have whole genome matches with the outbreak strain.

In my tracking of foodborne pathogens associated with raw or fresh consumed (uncooked/heated) sprouted seeds, I have collected information on 79 outbreaks resulting in 11,498 confirmed illnesses since 1973 (see attachment A, Sprout-associated--outbreaks-4-5-21.xls). Numerous pathogens have either been implicated in sprout-associated outbreaks, including *Bacillus cereus*, *Listeria monocytogenes*, *Shigella spp*. and *Yersinia enterocolitica*. But the vast majority of illnesses (well over 90 %) have been due to *Salmonella* enterica serovars and Shiga toxin-producing *Escherichia coli*, both pathogens that have been identified as contributing to a high public health burden. The majority of these outbreaks have been linked to a contaminated seed source or sanitation in sprouting – both supplier issues that can be exacerbated by a poor food safety culture where standards are not set, and where buyers do not evaluate what practices are being implemented.

In 2011, a landmark outbreak of *E. coli* O104 linked to sprouted seeds led to 53 deaths and over 4,000 sick people (Altmann et al, 2011). This outbreak dominated the food safety popular press, trade magazines, online listservs, and food safety blogs. It would have been very difficult for any food safety professional not to see this coverage. As a result, since that time (if not before), when asked what foods they avoid based on their knowledge of contamination and history, food safety professionals often list raw sprouted seed at the top of the list. In a 2019 retrospective study of foodborne pathogens associated with fresh produce, derived from multistate foodborne outbreaks of bacterial infection in the U.S. from 2010 to 2017, the most frequently identified food vehicle within the vegetable category was sprouts (27.6% of all outbreaks) (Carstens et al. 2019). In 2021, the FDA also completed a risk-ranking model to support food safety intervention resources for foods in the U.S., and this model identified sprouts as tied for fourth on the list of risky foods (ahead of shellfish, fresh cut leafy greens and some cheeses) (FDA, 2021). The CDC still specifically lists sprouts as a risky food on their public communication related to avoiding food poisoning, accompanied by the statement "Some foods are more associated with foodborne illnesses and food poisoning than others. They can carry harmful germs that can make you very sick if the food is contaminated." (CDC, 2020)

Jimmy John's Franchise, LLC has a history of sprouted seed-linked outbreaks prior to the 2020 event (Sol Erdozain et al, 2013). After two previous outbreaks in 2008 and 2009, a third Jimmy John's, LLC/sprout-linked outbreak occurred from November 2010 into 2011, leading to 140 illnesses (CDC, 2011; Illinois Department of Public Health, 2010). By the end of December 2010, a sprout supplier, Tiny Greens Farm, was implicated in the outbreak (FDA, 2010). Jimmy John's owner, John Liautaud, responded by stating the sandwich chain would replace alfalfa sprouts with clover sprouts since they were allegedly easier to clean (Associated Press, 2011).

In FDA's investigation of the Tiny Greens facility numerous failures were found which may have led to pathogen contamination. According to the FDA report, "the company grew sprouts in soil from the organic material decomposed outside without using any monitored kill step on it," mold was found in the mung-bean sprouting room, and the antimicrobial treatment for seeds was not demonstrated to be equivalent to the recommended FDA treatment (Roos, 2011).

In late December 2011, less than one year after making the switch to clover sprouts, Jimmy John's Franchise, LLC was linked to a fourth sprout related outbreak, *E.coli* O26 (CDC, 2012). In February 2012, sandwich franchise Jimmy John's Franchise, LLC announced they were permanently removing raw clover sprouts from their menus (Liddle, 2012; Sol Erdozain et al, 2013). But sprouted seeds did return to menus, resulting in the 2020 outbreak.

Sprouted seeds have been removed from a variety of other businesses. For example, Erbert and Gerbert's Sandwich Shops removed alfalfa sprouts from their menu, Walmart stores stopped selling raw sprouts nationwide in 2010, and Kroger followed suit in 2012. Other restaurants have chosen to not sell sprouted seeds in new menu items as a precaution (Denn, 2012; Huffington Post 2012).

In my professional opinion, the February 2020 warning letter from FDA to Jimmy John's about continuous use of sprouts is unique. In my professional experience reviewing warning letters and working with businesses to respond to regulatory actions, I have never seen a situation like this, where a firm said they would do something in an official meeting with FDA, and then eventually decided to do something else (FDA, 2020).

From that letter, "In May 2012, a meeting was held with FDA at your request. During that meeting, you expressed that you would offer only clover sprouts, and to only source clover sprouts from [redacted] suppliers.

Since that corrective action, your firm has been implicated in three additional sprout-related outbreaks. Documents from traceback investigations conducted by FDA, states and local partners demonstrate that in addition to [redacted] sprouts, Jimmy John's restaurants are using multiple other sources of sprouts."

As a response to the multiple outbreaks, Jimmy John's Franchise, LLC has included various risk messages including in online orders, where a less than appetizing warning pops up: "The consumption of raw sprouts may result in an increased risk of foodborne illness and poses a health risk to everyone. Click 'Yes' if you understand the potential risks, or 'Cancel' if you'd like to continue without adding sprouts."

In stores, one response was to include a poster of a skull and cross bone picture and the following text:

"THE CONSUMPTION OF RAW SPROUTS MAY RESULT IN AN INCREASED RISK OF FOODBORNE ILLNESS AND POSES A HEALTH RISK TO EVERYONE. EXPECTANT MOTHERS, DAREDEVILS, CUTE OLD LADIES, INFANTS, VEGANS & VEGETARIANS, GRUMPY OLD MEN, INVINCIBLE TEENAGERS, YOUR AVERAGE JOE, PERSONS

WITH WEAKENED IMMUNE SYSTEMS AND EVEN THE STRONGEST SUPERHEROES, PLEASE BEWARE. IF YOU DON'T BELIEVE ME, CONTACT YOUR PHYSICIAN OR LOCAL PUBLIC HEALTH DEPARTMENT! CHILDREN UNDER 18 MUST GET THEIR PARENTS' PERMISSION."

In my professional opinion, keeping sprouted seeds on the menu and then taunting consumers with sassy posters showing a cartoon and campy text was a brazen move by Jimmy John's Franchise, LLC, and goes against good risk communication practices. Risk communication research has revealed that consumers need to understand the context of a risk to be able to identify and employ informed decision making. Familiarity also plays a strong role in consumer perception of a risk, as does trust. Behavior and risk communication are more likely to be impacted when targeting both knowledge and individual intention.

Making light of the numerous outbreaks and thousands of illnesses that have been linked to these products is not really in line with what Jimmy John's CEO James North said following one of the previous outbreaks: "Food safety and the welfare of our customers are our top priorities and not negotiable in our business." (Pantagraph Staff, 2018)

Passing the responsibility to consumers to conduct their own risk assessments, as Jimmy John's Franchise, LLC has consistently done over the last 15 years relies on solid validation that the practices (avoidance and controlling cross-contamination) will work and a keen focus on effective risk communication to allow for consumers to make an informed decision. In my professional opinion, and from viewing documents related to this case, previous cases and those that are publicly available, Jimmy John's Franchise, LLC does not appear to acknowledge the history or risks of consuming raw sprouted seeds, and has not learned from their past issues. The firm appears to have a poor food safety culture, has left risk reduction decisions in the hands of their patrons, and they have not armed them with the tools to do so.

Benjamin Chapman, PhD

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Foodborne Illness Outbreaks Associated with Sprouts				
Date	**Causative Agent**	**Illnesses Reported**	**Source**	**Country of Outbreak**
Jan 2020 - Mar 2020	*E. coli* O103	51	Clover sprouts	Multistate, U.S.: https://www.cdc.gov/ecoli/2020/o103h2-02-20/index.html
Nov 2019 - Dec 2019	*E. coli* O103	22	Clover sprouts	Iowa, U.S.: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jimmy-johns-franchise-llc-599962-02212020
Dec 2017-Jan 2018	*Salmonella* Montevideo	10	Sprouts	Multistate, U.S.: https://www.cdc.gov/salmonella/montevideo-01-18/index.html
May-July 2016	*Salmonella*	30	Alfalfa sprouts	Multistate, U.S.: http://www.foodsafetynews.com/2016/08/fresh-sprouts-from-denver-linked-to-9-state-outbreak/#.WXeKjBTZqf4
Apr. 2016	*Salmonella* Saintpaul	244	Mung bean sprouts	Australia.: http://www.adelaidenow.com.au/news/south-australia/extra-five-cases-in-sa-for-bean-sprout-contamination/news-story/a3579929ba487a9acbcfaa46b58afcb7
Jan. 2016	*E. coli* O157	11	Alfalfa sprouts Jack & The Green Sprouts (Wisconsin)	Minnesota, U.S.: https://www.cdc.gov/ecoli/2016/o157-02-16/index.html
Nov. 2015-Jan. 2016	*Salmonella* Muenchen	13	Alfalfa sprouts from Sweetwater Farms (Kansas)	Multistate, U.S.: http://www.cdc.gov/salmonella/enteritidis-11-14/; http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm424426.htm
Sep. 2014	*Salmonlla* Enteriditis	115	Bean sprouts produced by Wonton Foods	Multistate, U.S.: http://www.cdc.gov/salmonella/enteritidis-11-14/; http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm424426.htm
Jun.-Aug. 2014	*Listeria monocytogenes*	5	Mung brean sprouts produced by Wholesome Soy Products	Illinois and Michigan, U.S.: http://www.cdc.gov/listeria/outbreaks/bean-sprouts-11-14/index.html; http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm422562.htm
May. 2014	*E. coli* O121	19	Raw clover sprouts produced by Evergreen Fresh Sprouts, LLC of Idaho are likely source	Washington and Idaho, U.S.: http://www.cdc.gov/ecoli/2014/o121-05-14/index.html; http://www.doh.wa.gov/Newsroom/2014NewsReleases/14070CloverSproutsSourceofEColiOutbreak

Jul. 2012	*Salmonella* Cubana	19	Sprouts, unspecified	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Mar. 2012	*Listeria monocytogenes*	6	Sprouts, unspecified	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Dec. 2011-Feb. 2012	*E. coli* O26	29	Raw clover sprouts at Jimmy John's restaurants is the likely cause of this outbreak	Multistate, U.S.: http://www.cdc.gov/ecoli/2012/O26-02-12/index.html; http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Aug. 2011	*Salmonella* Agona	7	Sprouts, unspecified	Kansas, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Apr.-Jul. 2011	*Salmonella* Enteritidis	27	Alfalfa sprouts and spicy sprout produced by Evergreen Fresh Sprouts, LLC	Idaho, Montana, North Dakota, New Jersey and Washington, U.S.: http://www.cdc.gov/salmonella/sprouts-enteritidis0611/070611/index.html; http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
May-Jul. 2011	*E. coli* O104:H4	4,075	Bean sprouts	Europe, Canada and U.S.: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6250a3.htm; Buchholz, U., Bernard, H., Werber, D., Böhmer, M. M., Remschmidt, C., Wilking, H., ... & Kühne, M. (2011). German outbreak of Escherichia coli O104: H4 associated with sprouts. New England Journal of Medicine, 365(19), 1763-1770. https://www-s.med.illinois.edu/m2/epidemiology/LiteratureCritique/pdf/Buchholz_2011.pdf
Apr. 2011	*Salmonella* Muenchen	7	Clover sprouts	Michigan, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Dec. 2010-Jan. 2011	*Salmonella* Newport	9	Clover sprouts produced by Sprouters Northwest, Inc., of Kent, WA	Oregon and Washington, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx; http://www.doh.wa.gov/Portals/1/Documents/1500/NewsReleases/2011/11-001CloverSproutsRecall.pdf
Dec. 2010	*Salmonella* Cubana	3	Alfalfa sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Nov. 2010-Feb. 2011	*Salmonella* serotype I 4,[5],12:i:-	140	Alfalfa sprouts	Multistate, U.S.: http://www.cdc.gov/salmonella/i4512i-/021011/index.html; http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx

Aug.-Oct. 2010	*Salmonella* Bareilly	190	Bean sprouts	U.K.: http://www.hpa.org.uk:80/webw/HPAweb&HPAwebStandard/HPAweb_C/1287143210927?p=1259152466069
Mar.-Jun. 2010	*Salmonella* Newport	44	Alfalfa sprouts produced by J.H. Caldwell and Sons Inc. of Maywood, CA	Multistate, U.S.: http://www.cdc.gov/salmonella/newport/; http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Feb. 2010	unknown	4	Sprouts, unspecified	Colorado, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Aug. 2009	*Salmonella* Typhimurium	14	Alfalfa sprouts	Michigan, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Jun. 2009	*Salmonella* Bovismorbificans	42	Ready-to-eat alfalfa sprouts	Finland: Rimhanen-Finne, R., Niskanen, T., Lienemann, T., Johansson, T., Sjöman, M., Korhonen, T., Guedes, S., Kuronen, H., Virtanen, M. J., Mäkinen, J., Jokinen, J., Siitonen, A. and Kuusi, M. (2011), A Nationwide Outbreak of Salmonella Bovismorbificans Associated with Sprouted Alfalfa Seeds in Finland, 2009. Zoonoses and Public Health, 58: 589–596. http://onlinelibrary.wiley.com/doi/10.1111/j.1863-2378.2011.01408.x/abstract
Apr.-Jul. 2009	*Salmonella* Cubana	14	Onion sprouts and mixed onion/alfalfa sprout	Canada: http://www.bccdc.ca/resourcematerials/newsandalerts/healthalerts/2009HealthAlerts/SalmonellaCubanaOutbreak_aug24.htm
Apr. 2009	*Salmonella* Cubana	2	Sprouts, unspecified	Minnesota, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Feb.-May. 2009	*Salmonella* Saintpaul	256	Raw alfalfa sprouts	Multistate, U.S.: http://www.cdc.gov/salmonella/saintpaul/alfalfa/; http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5818a4.htm
Feb. 2009	*Salmonella* Oranienberg	25	Alfalfa sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Sep. 2008	*E. coli* O157:NM	21	Alfalfa sprouts; iceberg lettuc, unspecified	Colorado, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Jul. 2008	*Salmonella* Typhimurium	24	Alfalfa sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/default.aspx; http://www.fda.gov/safety/recalls/archiverecalls/2008/ucm112494.htm

Mar. 2008	*Listeria monocytogenes*	20	Sprouts, unspecified	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Jul.-Oct. 2007	*Salmonella* Weltevreden	45	Alfalfa sprouts	Denmark, Norway and Finland: Emberland KE, Ethelberg S, Kuusi M, Vold L, Jensvoll L, Lindstedt BA, Nygård K, Kjelsø C, Torpdahl M, Sørensen G, Jensen T, Lukinmaa S, Niskanen T, Kapperud G. Outbreak of Salmonella Weltevreden infections in Norway, Denmark and Finland associated with alfalfa sprouts, July-October 2007. Euro Surveill. 2007;12(48):pii=3321. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=3321
Jul.-Aug. 2007	*Salmonella* Stanley	44	Alfalfa sprouts	Sweden: Werner S, Boman K, Einemo I, Erntell M, de Jong B, Lindqvist A, Löfdahl M, Löfdahl S, Meeuwisse A, Ohlen G, Olsson M, Stamer U, Sellström E, Andersson Y. Outbreak of Salmonella Stanley in Sweden associated with alfalfa sprouts, July-August 2007. Euro Surveill. 2007;12(42):pii=3291. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=3291
Apr. 2007	*Salmonella* Mbandaka	15	Alfalfa sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Feb. 2006	*Salmonella* Braenderup	4	Bean sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Nov. 2005	*Salmonella* Oranienberg	125	Alfalfa sprouts	Australia: http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3003b.htm
Nov. 2005	*Salmonella* Braenderup	2	Mung sprouts	Massachusetts, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Oct.-Dec. 2005	*Salmonella spp.*	648	Mung sprouts	Canada: http://news.ontario.ca/archive/en/2005/12/14/Update-on-Salmonella-Outbreak.html; Outbreak of *Salmonella entertidis* phage type 13 associated with mung bean sprouts in Ontario, 2005. Outbreak Investigation. May 17. 2006. http://www.sproutnet.com/pdfs/Toronto-Mung-2005.pdf
Apr. 2004	*E. coli* O157:NM	2	Alfalfa sprouts	Georgia, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx

Apr. 2004	*Salmonella* Bovismorbificans	35	Raw alfalfa sprouts produced by Sprouters Northwest, Inc., of Kent, WA	Oregon and Washington, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx; http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108307.htm
Nov. 2003	*Salmonella* Chester	26	Alfalfa sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Jul. 2003	*E. coli* O157:NM	13	Alfalfa sprouts	Colorado, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx; D. D. Ferguson, J. Scheftel, A. Cronquist, K. Smith, A. Woo-Ming, E. Anderson J. Knutsen, A. K. De and K. Gershman (2005). Temporally distinct Escherichia coli O157 outbreaks associated with alfalfa sprouts linked to a common seed source – Colorado and Minnesota, 2003. Epidemiology and Infection, 133, pp 439-447. http://dx.doi.org/10.1017/S0950268804003589
Feb. 2003	*Salmonella* Saintpaul	16	Alfalfa sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Feb. 2003	*E. coli* O157:H7	7	Alfalfa sprouts	Minnesota, U.S.: D. D. Ferguson, J. Scheftel, A. Cronquist, K. Smith, A. Woo-Ming, E. Anderson J. Knutsen, A. K. De and K. Gershman (2005). Temporally distinct Escherichia coli O157 outbreaks associated with alfalfa sprouts linked to a common seed source – Colorado and Minnesota, 2003. Epidemiology and Infection, 133, pp 439-447. http://dx.doi.org/10.1017/S0950268804003589
Jan. 2003	*E. coli* O157:H7	20	Alfalfa sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Jul. 2002	*E. coli* O157:H7	5	Alfalfa sprouts	California, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Apr. 2001	*Salmonella* Entertidis	35	Mung sprouts	Florida, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Feb. 2001	*Salmonella* Kottbus	32	Alfalfa sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Jan. 2001	*Salmonella* Entertidis	22	Mung sprouts	Hawaii, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx

Feb.-Mar. 2001	*Salmonella* Enteritidis	84	Mung sprouts	Canada: Honish, L., & Nguyen, Q. (2001). Outbreak of Salmonella enteritidis phage type 913 gastroenteritis associated with mung bean sprouts--Edmonton, 2001. Canada communicable disease report= Relevé des maladies transmissibles au Canada, 27(18), 151. http://www.sproutnet.com/Outbreak-of-Salmonella-in-Canada
Oct. 2001	unknown	2	Alfalfa sprouts	Florida, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Nov. 2000	*S. Enteritidis* phage type 4b	12	Bean sprouts	Netherlands: van Duynhoven, Y. T., Widdowson, M. A., de Jager, C. M., Fernandes, T., Neppelenbroek, S., van den Brandhof, W., ... & van Pelt, W. (2002). Salmonella enterica serotype Enteritidis phage type 4b outbreak associated with bean sprouts. Emerging infectious diseases, 8(4), 440. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2730240/
May. 2000	*Salmonella enterica*	3	Alfalfa spouts (suspected)	Florida, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
2000	*Salmonella* Enteritidis	75	Mung sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Apr.-Jun. 2000	*Salmonella* Enteritidis	12	Mung sprouts	Canada: Harb, J., Isaacs, S., Fyfe, M., Crowe, L., Slater, B., Ahmed, R., ... & Hockin, J. (2003). Outbreak of Salmonella enteritidis phage type 11B in the provinces of Alberta and Saskatchewan, June 2000. Canada communicable disease report= Relevé des maladies transmissibles au Canada, 29(14), 125. http://www.sproutnet.com/Outbreak-of-Salmonella-Enteritidis
Aug.-Sep. 1999	*Salmonlla* Muenchen	157	Alfalfa sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx; Proctor, M. E., Hamacher, M., Tortorello, M. L., Archer, J. R., & Davis, J. P. (2001). Multistate outbreak of Salmonella serovar Muenchen infections associated with alfalfa sprouts grown from seeds pretreated with calcium hypochlorite. Journal of clinical microbiology, 39(10), 3461-3465.
May. 1999	*Salmonella* Saintpaul	36	Clover sprouts	California, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx

Jan. 1999	*Salmonella* Mbandaka	83	Alfalfa sprouts	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx; Gill, C. J., Keene, W. E., Mohle-Boetani, J. C., Farrar, J. A., Waller, P. L., Hahn, C. G., & Cieslak, P. R. (2003). Alfalfa seed decontamination in Salmonella outbreak. Emerging infectious diseases, 9(4), 474. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2957971/
Jan. 1999	*Salmonella* Typhimurium	112	Clover sprouts	Colorado, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx; Brooks, J. T., Rowe, S. Y., Shillam, P., Heltzel, D. M., Hunter, S. B., Slutsker, L., ... & Luby, S. P. (2001). Salmonella Typhimurium infections transmitted by chlorine-pretreated clover sprout seeds. American journal of epidemiology, 154(11), 1020-1028. http://aje.oxfordjournals.org/content/154/11/1020.short
Aug.-Sep. 1999	*S. paratyphi* B var java	51	Alfalfa sprouts	Canada: Stratton, J., Stefaniw, L., Grimsrud, K., Werker, D. H., Ellis, A., Ashton, E., ... & Jensen, B. (2001). Outbreak of Salmonella paratyphi B var java due to contaminated alfalfa sprouts in Alberta, British Columbia and Saskatchewan. Canada communicable disease report= Relevé des maladies transmissibles au Canada, 27(16), 133. http://www.sproutnet.com/Outbreak-of-Salmonella-Paratyphi
Jun. 1998	*E. coli* O157:NM	8	Alfalfa sprouts	California, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
May. 1998	*Salmonella* Havana and Cubana	40	Alfalfa sprouts (Havana suspected)	Multistate, U.S.: http://wwwn.cdc.gov/foodborneoutbreaks/Default.aspx
Jun.-Jul. 1997	E. coli O157:H7	82	Alfalfa sprouts	Michigan and Virginia, U.S.: Breuer, T., Benkel, D. H., Shapiro, R. L., Hall, W. N., Winnett, M. M., Linn, M. J., ... & Team, I. (2001). A multistate outbreak of Escherichia coli O157: H7 infections linked to alfalfa sprouts grown from contaminated seeds. Emerging infectious diseases, 7(6), 977. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2631892/pdf/11747724.pdf; http://www.cdc.gov/mmwr/preview/mmwrhtml/00048994.htm

1997	*Salmonella* Infantis and Anatum	109	Alfalfa sprouts	Kansas and Missouri, U.S.: Taormina, P. J., Beuchat, L. R., & Slutsker, L. (1999). Infections associated with eating seed sprouts: an international concern. Emerging Infectious Diseases, 5(5), 626. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627711/pdf/10511518.pdf; Glynn, M. K., Patrick, S., & Wuhib, T. (1998, April). When health food isn't so healthy—an outbreak of Salmonella serotypes Anatum and Infantis associated with eating contaminated sprouts, Kansas and Missouri, 1997. In 47th Annual Epidemic Intelligence Service (EIS) Conference. Atlanta, GA: Centers for Disease Control and Prevention.
Sep. 1997-Jul. 1998	*Salmonella* Senftenberg	60	Alfalfa sprouts	California and Nevada, U.S.: Mohle-Boetani, J. C., Farrar, J. A., Werner, S. B., Minassian, D., Bryant, R., Abbott, S., ... & Vugia, D. J. (2001). Escherichia coli O157 and Salmonella infections associated with sprouts in California, 1996–1998. Annals of Internal Medicine, 135(4), 239-247. http://annals.org/article.aspx?articleid=714688
1997	*Salmonella* Meleagridis	78	Alfalfa sprouts	Canada: Taormina, P. J., Beuchat, L. R., & Slutsker, L. (1999). Infections associated with eating seed sprouts: an international concern. Emerging Infectious Diseases, 5(5), 626. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627711/pdf/10511518.pdf
1997	*E. coli* O157:H7	126	Radish sprouts	Japan: Taormina, P. J., Beuchat, L. R., & Slutsker, L. (1999). Infections associated with eating seed sprouts: an international concern. Emerging Infectious Diseases, 5(5), 626. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627711/pdf/10511518.pdf; Gutierrez, E. (1997). Japan prepares as 0157 strikes again. The Lancet, 349(9059), 1156.
May.-Jul. 1996	*Salmonella* Meleagridis and Montevideo	500	Alfalfa and clover sprouts	California and Nevada, U.S.: Mohle-Boetani, J. C., Farrar, J. A., Werner, S. B., Minassian, D., Bryant, R., Abbott, S., ... & Vugia, D. J. (2001). Escherichia coli O157 and Salmonella infections associated with sprouts in California, 1996–1998. Annals of Internal Medicine, 135(4), 239-247. http://annals.org/article.aspx?articleid=714688

1996	*E. coli O157:H7*	6,000	Radish sprouts	Japan: Watanabe, Y., Ozasa, K., Mermin, J. H., Griffin, P. M., Masuda, K., Imashuku, S., & Sawada, T. (1999). Factory outbreak of Escherichia coli O157: H7 infection in Japan. Emerging infectious diseases, 5(3), 424. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2640759/pdf/10341179.pdf
1995-1996	*Salmonella* Newport	133	Alfalfa sprouts	U.S., Canada and Denmark: Taormina, P. J., Beuchat, L. R., & Slutsker, L. (1999). Infections associated with eating seed sprouts: an international concern. Emerging Infectious Diseases, 5(5), 626. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627711/pdf/10511518.pdf. Van Beneden, C. A., Keene, W. E., Strang, R. A., Werker, D. H., King, A. S., Mahon, B., ... & Fleming, D. (1999). Multinational outbreak of Salmonella enterica serotype Newport infections due to contaminated alfalfa sprouts. Jama, 281(2), 158-162.; Wegener HC, Baggesen DL, Neimann J, Nielsen SV. An outbreak of human salmonellosis in Denmark caused by alfalfa sprouts. In: Proceedings and abstracts of the International Symposium on Salmonella and Salmonellosis; Ploufragan, France; May 20-22, 1997:587-589.
1995	*Salmonella* Stanley	242	Alfalfa sprouts	Finland and U.S.: Mahon, B. E., Pönkä, A., Hall, W. N., Komatsu, K., Dietrich, S. E., Siitonen, A., ... & Slutsker, L. (1997). An international outbreak of Salmonella infections caused by alfalfa sprouts grown from contaminated seeds. Journal of Infectious Diseases, 175(4), 876-882. http://jid.oxfordjournals.org/content/175/4/876.full.pdf?origin=publication_detail
1994	*Salmonella* Newport	154	Alfalfa sprouts	Denmark: WHO Surveillance Programe for Control of Foodborne Infections and Intoxications in Europe, 7th Report: Denmark 1993-1998. http://www.bfr.bund.de/internet/7threport/CRs/den.pdf

1994	*Salmonella* Bovismorbificans	595	Australian alfalfa sprouts seed	Sweden and Finland: Taormina, P. J., Beuchat, L. R., & Slutsker, L. (1999). Infections associated with eating seed sprouts: an international concern. Emerging Infectious Diseases, 5(5), 626. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627711/pdf/10511518.pdf; Puohiniemi, R., Heiskanen, T., & Siitonen, A. (1997). Molecular epidemiology of two international sprout-borne Salmonella outbreaks. Journal of clinical microbiology, 35(10), 2487-2491. http://jcm.asm.org/content/35/10/2487.full.pdf; Pönkä, A., Andersson, Y., Siitonen, A., de Jong, B., Jahkola, M., Haikala, O., ... & Pakkala, P. (1995). Salmonella in alfalfa sprouts. The Lancet, 345(8947), 462-463.
Oct. 1990	*Salmonella* Anatum	15	Alfalfa sprouts	Washington, U.S.: http://www.cdc.gov/outbreaknet/pdf/surveillance/1990_linelist.pdf
Oct. 1990	unknown	32	Alfalfa sprouts, cucumber, lettuce	Washington, U.S.: http://www.cdc.gov/outbreaknet/pdf/surveillance/1990_linelist.pdf
1989	*Salmonella G*oldcoast	31	Cress sprouts	U.K.: Taormina, P. J., Beuchat, L. R., & Slutsker, L. (1999). Infections associated with eating seed sprouts: an international concern. Emerging Infectious Diseases, 5(5), 626. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627711/pdf/10511518.pdf; Joce, R., O'Sullivan, D. G., Strong, C., Rowe, B., Hall, M. L. M., & Threlfall, E. J. (1990). A national outbreak of Salmonella Gold-Coast. Commun Dis Rep CDR Rev, 4, 3-4.
1988	*Salmonella* Saintpaul and Virchow PT34 (7cases)	143	Mung sprouts	U.K.: O'mahony, M., Cowden, J., Smyth, B., Lynch, D., Hall, M., Rowe, B., ... & Bartlett, C. L. R. (1990). An outbreak of Salmonella saint-paul infection associated with beansprouts. Epidemiology and infection, 104(02), 229-235. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2271762/pdf/epidinfect00020-0070.pdf
1973	*Bacillus cereus*	4	Soy, cress, mustard sprouts	U.S.: Portnoy, B. L., Goepfert, J. M., & Harmon, S. M. (1976). An outbreak of Bacillus cereus food poisoning resulting from contaminated vegetable sprouts. American journal of epidemiology, 103(6), 589-594.

Exhibit C

WARNING LETTER

Jimmy John's Franchise, LLC

MARCS-CMS 599962 — FEBRUARY 21, 2020

Delivery Method:
Certified Mail
Product:
Food & Beverages

Recipient:
James North
President
Jimmy John's Franchise, LLC
2212 Fox Drive
Champaign, IL 61820
United States

Issuing Office:
Division of Human and Animal Food Operations East VI
United States

WARNING LETTER

FY2020-HAFE6-01

Dear Mr. North:

The U.S. Food and Drug Administration (FDA), along with the Centers for Disease Control and Prevention (CDC), and state and local partners, have collaboratively investigated several outbreaks linked to Jimmy John's restaurants. In this letter we detail evidence from five outbreaks, including the most recent outbreak in the state of Iowa during December 2019 of human infections with *Escherichia coli* O103. The evidence demonstrates that your corporation, through your franchised Jimmy John's restaurants, engaged in a pattern of receiving and offering for sale adulterated fresh produce, specifically clover sprouts and cucumbers.

The pathogens associated with these outbreaks are Shiga toxin producing *Escherichia coli* (STECs) and *Salmonella enterica*. STECs can cause serious illness in humans, including diarrhea, often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called hemolytic uremic syndrome (HUS). HUS is most likely to occur in young children and the elderly. This condition can lead to serious kidney damage and death. *Salmonella* is a

pathogenic bacterium that can cause serious, sometimes fatal, infections. These infections can be especially serious in young children, the elderly, and others with weakened immune systems. Healthy individuals may suffer short-term symptoms such as severe diarrhea, bloody diarrhea, fever, chills, abdominal discomfort, and vomiting. The presence of these pathogens in your food, as evidenced by links to foodborne outbreaks, causes your products to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act)[21 U.S.C. § 342(a)(1)] in that they bear or contain an added poisonous or deleterious substance which may render them injurious to health. The introduction or delivery for introduction into interstate commerce of food that is adulterated is a prohibited act under section 301(a) of the Act [21 U.S.C. 331(a)]. Further, receipt in interstate commerce of adulterated food is a prohibited act under section 301(c) of the Act [21 U.S.C. § 331(c)]. You can find the Act and its implementing regulations through links on FDA's home page at https://www.fda.gov.

Human Illness Outbreaks

1. November to December 2019; outbreak of human infections with *E. coli* O103 (STEC)

Iowa Department of Public Health reported that as of January 7, 2020, a total of 22 people from Iowa were infected with the outbreak strain of *E. coli* O103. Twenty of the 22 case individuals were interviewed by the Iowa Department of Public Health. Of the case individuals interviewed, 100 % reported eating at one or more of 15 Jimmy John's restaurants. Of the 20 interviewed, 45% (9) reporting eating sprouts in the week before their illness. Iowa Department of Public Health states this proportion is significantly higher than results from a survey of healthy people in which 3.3% reported eating sprouts in the seven days before being interviewed.

Iowa Department of Inspections and Appeals ascertained that **(b)(4)** of the 15 Jimmy John's restaurants received clover sprouts from **(b)(4)** clover sprouts during the period of interest. As further confirmation that sprouts served at your restaurants were the outbreak vehicle, samples of sprouts and sprout irrigation water collected by the firm that supplied the **(b)(4)** Jimmy John's restaurants yielded a strain of *E. coli* O103 that was highly related to the outbreak strain by whole genome sequencing, a state-of-the-art genetic subtyping method. The analytical work was done by **(b)(4)**.

2. Outbreak of human infections with *Salmonella* Montevideo

The CDC reported that as of February 28, 2018, ten people were infected with the outbreak strains of *Salmonella* Montevideo in Illinois (2), Minnesota (2), and Wisconsin (6). Eight (80%) of these ten people ate meals at Jimmy John's restaurants in Illinois and Wisconsin the week before becoming sick. All eight people reported eating raw sprouts on sandwiches from Jimmy John's in Illinois and Wisconsin. One ill person in this outbreak reported eating raw sprouts purchased from a grocery store in Minnesota. All the *Salmonella* Montevideo isolates were closely related by whole genome sequencing.

The evidence supports that **(b)(4)** sprouts for the implicated Jimmy John's restaurants. **(b)(4)** shown in invoices collected by State and local partners, including the Illinois Department of Public Health, Minnesota Department of Health, the Minnesota Department of Agriculture, the Wisconsin Department of Agriculture, Trade and Consumer Protection, and the Wisconsin Department of Health Services, from various Jimmy John's locations the Minnesota grocery store and/or distributors.

3. Outbreak of human infections with E. coli O102 (STEC)

The CDC reported that as of August 1, 2014, 19 people were infected with the outbreak strain of *E. coli* O121 in Idaho, Montana, Michigan, Utah, California, and Washington. In interviews, 13 (81%) of 16 ill persons reported eating raw clover sprouts in the week before becoming ill. This proportion is significantly higher than results from a survey of healthy persons in which no more than 8% reported eating raw clover sprouts in the week before they were interviewed.

FDA's traceback investigation for 11 of the 19 case individuals identified seven points of service [POS] as the likely or most likely locations of their sprout exposures. Five (5) of seven (7) POS were identified as Jimmy John's restaurants. Clover sprouts served at each POC were sourced from the same sprout grower.

4. Outbreak of human infections with E. coli O157:H7 (STEC)

CDC reported that as of the end of October 2013, eight people from Colorado were infected with the outbreak strain of *E. coli O157:H7*. Of the eight persons interviewed by Colorado Department of Public Health and Environment, 100% report eating a sandwich with raw cucumbers at one of three Jimmy John's restaurants in the Denver metro area. No other ingredient exposure was as significant as cucumbers. FDA's traceback investigation identified that all three Jimmy John's restaurants involved in the outbreak received cucumbers from the same source during the period of interest.

5. Outbreak of human infections with E. coli O26

CDC reported that as of April 5, 2012, a total of 29 people from eleven states were infected with an outbreak strain of *E. coli O26*. Of the 27 persons interviewed, 85% (23) report eating sprouts at one of six Jimmy John's restaurant in the seven days preceding their illness. Though traceback investigation, FDA identified a single lot of seed grown and distributed by multiple sprouting firms including **(b)(4)** sprout operations that supplied the six Jimmy John's restaurants implicated in the outbreak.

Taken together, these outbreaks, which spanned over the past seven years and impacted no fewer than seventeen states demonstrate the corporate-wide supplier control mechanisms you have in place for receiving fresh produce are inadequate.

We acknowledge your parent company's, Inspire Brands, decision in December 2019 to destroy sprouts on hand in all of your Iowa Jimmy John's restaurants, and to implement an additional, one-time cleaning and sanitation at Iowa based Jimmy John's restaurants; however, neither you nor your parent company proposed any corrective actions to prevent these, or other Jimmy John's restaurants, from receiving adulterated produce, specifically sprouts. According to your website, www.ownajimmyjohns.com (http://www.ownajimmyjohns.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), you have franchised approximately 2,800 Jimmy John's restaurants in 43 states. In your response to this letter, please describe and document steps you have or will take to prevent the receipt and sale of adulterated food at each of the approximately 2,800 Jimmy John's restaurants.

In May 2012, a meeting was held with FDA at your request. During that meeting, you expressed that you would offer only clover sprouts, and to only source clover sprouts from **(b)(4)** suppliers. Since that corrective action, your firm has been implicated in three additional sprout-related outbreaks. Documents from traceback investigations conducted by FDA, states and local partners demonstrate that in addition to **(b)(4)** sprouts, Jimmy John's restaurants are using multiple other sources of sprouts.

Although you stated that corrective actions were implemented following the 2019 and 2012 outbreaks, you have not provided FDA with any information demonstrating long-term, sustainable corrections have been implemented throughout your organization to prevent this violation from recurring in the future. For example, providing FDA with documentation of policies and practices demonstrating that you have made a corporate commitment to ensure produce covered by the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule), Title 21 Code of Federal Regulations, Part 112 (21 CFR Part 112), specifically sprouts, and sourced by any Jimmy John's restaurant will be procured from a farm or firm operating in compliance with the Produce Safety Rule, the Act, and, as applicable, the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods (PC Rule), 21 CFR Part 117.

The above violations are not intended to be an all-inclusive list of violations that exist in connection with the food you receive and offer for sale at your restaurants. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure your firm

complies with all requirements of federal law and implementing regulations. You should take prompt action to correct all violations noted in this letter. Failure to promptly correct these violations may result in enforcement action by FDA without further notice, including seizure and/or injunction.

Next Steps

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should include the specific things you are doing to address this violation. You should include in your response documentation and information that would assist us in evaluating your corrections. If you believe you have complied with the Act, include your reasoning and any supportive information for our consideration. If you cannot complete all corrections within 15 days, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to Food and Drug Administration, Attention: Lauren Crivellone Compliance Officer, Office of Human and Animal Foods Operations, Division East Six, Compliance Branch, 550 West Jackson Boulevard, Suite 1500, Chicago, Illinois 60661. If you have any questions regarding this letter, you may contact Compliance Officer Crivellone via email at Lauren.Crivellone@fda.hhs.gov (mailto:Lauren.Crivellone@fda.hhs.gov). Please reference CMS # 599962 on any documents or records you provide to us and/or within the subject line of any email correspondence you send to us.

Sincerely,

/S/
William R. Weissinger, Program Division Director
Office of Human and Animal Foods
Division East 6

cc:

Paul J. Brown, Chief Executive Officer
Inspire Brands, Inc.
Three Glenlake Parkway NE
Atlanta, Georgia 30328

Paul J. Brown, Chief Executive Officer
Inspire Brands, Inc.
1155 Perimeter Center West, 12th Floor
Sandy Springs, Georgia 30338

Paul D. Ginsberg, President
Roark Capital Group
540 Madison Avenue Ste 37
New York, New York 10022

Paul D. Ginsberg, President
Roark Capital Group
1180 Peachtree Street NE, Suite 2500
Atlanta, Georgia 30309

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